IN THE UNITED STATES PATENT AND TRADEMARK OFFICE
BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

In re Application of:	:	
Sylvie Veriac, et al.	:	
Serial No.: 09/527,028	:	Art Unit: 1641
Filed: March 16, 2000	:	Examiner: Gabel, Gailene
For: Reagent for Determination of Leucocytes and Measurement of Haemoglobin in a Sample of Blood.	:	Atty Docket: 20198/00053

APPEAL BRIEF

MS Appeal Brief - Patents
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

As required under 37 CFR 41.37(a), this brief is filed within two months of the Notice of Appeal filed in this case on August 6, 2004, and is in furtherance of said Notice of Appeal.

The fees required under 37 CFR 41.20(b)(2), and any required petition for extension of time for filing this brief and fees therefore, are dealt with in the accompanying TRANSMITTAL OF APPEAL BRIEF.

This brief contains items under the following headings as required by 37 C.F.R. 41.37 and M.P.E.P. § 1206.

1. Whether the prior art would have suggested to those of ordinary skill in the art that they should make the claimed composition.

2. Whether the prior art would have suggested to those of ordinary skill in the art that the proposed combination carried a reasonable expectation of success.

B. Claim 14.

1. Reallegation of above arguments.

2. Whether the combination suggested by the Examiner forms an inoperable combination and therefore teaches away from the invention.

C. Conclusion.

IX. Claims Involved in the Appeal (Appendix A)

I. Real Party in Interest.

The Real Party In Interest Is Abx, Parc Euromedecine, 128 Rue Du Caducee, B.P. 7290, F-34184 Montpellier Cedex 4, France.

II. Related Appeals and Interferences.

There are no other appeals or interferences known to Appellant, Appellant's legal representative, or assignee which will directly affect or be directly affected by or have a bearing on the Board's Decision in this Appeal.

III. Status of Claims.

Claims 1-11 and 13 were cancelled.

Claims 12 and 14-24 are pending in the application.

Claims 12 and 14-24 were rejected and are the subject of this appeal.

IV. Status of Amendments.

Claims 12 and 14-24 were rejected under 35 U.S.C. § 112(1st) as failing to comply with the written description requirement. Claim 12 was rejected as reciting "and the absence of nonionic detergents." Claims 14-24 were rejected as incorporating said recitation by depending from Claim 12. The Applicant specifically denies any lack of compliance with the written

description requirement. However, in order to reduce issues for purposes of appeal, the applicant submits an Amendment, accompanying the present Brief, to amend Claim 12 to delete the recitation objected to.

Claims 14-24 are informal because they depend from cancelled Claim 1. Claims 14-24 are hereby amended merely to have them depend from Claim 12. No new matter is believed to be introduced by these amendments.

V. Summary of Claimed Subject Matter.

The invention relates to haematological analyses.[1] More particularly, the present invention concerns a single-solution[2] reagent permitting the determination of leucocytes and measurement of haemoglobin concentration in a sample of blood. The single-solution reagent of the present invention also allows for the quantification of the basophil polymorphonuclear leucocyte subpopulation.[3]

Leucocytes, or human white corpuscles, are divided into three main subpopulations: lymphocytes, monocytes, and polymorphonuclear leucocytes or granulocytes. Granulocytes are further subdivided into neutrophils, eosinophils, and basophils, according to the characteristics of their cytoplasmic granules.[4]

The determination of leucocytes, in particular of certain leucocytic subpopulations, as well as the measurement of the haemoglobin concentration of the erythrocytes or red corpuscles are very important for diagnosis in human pathology. [5]

Quantitation of basophilic granulocytes is tricky because in a healthy human, they represent only 0.5 to 1% of the total leucocyte population.[6] In various pathological conditions, the percentage of total leucocytes as basophils increases. For example, during the course of allergic reactions, basophils may become as much as 2 to 3% of total leucocytes. Basophilia may also be induced by infection, such as by tuberculosis and varicella, and by metabolic diseases, such as myxoedema and hyperlipidaemias.[7]

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[1] Page 1, line 5.
[2] Page 4, lines 13-14.
[3] Page 1, lines 11-13.
[4] Page 1, lines 21-27.
[5] Page 1, lines 15-19.
[6] Page 2, lines 1-5.
[7] Page 2, lines 7-13.

Haemoglobin is a chromoprotein contained in red blood cells (RBC, erythrocytes). Measurement of haemoglobin requires lysis of RBC. However, the required lytic agents are generally incompatible with preservation of basophils.[8] Traditionally, this incompatibility is mitigated by assaying haemoglobin in a first sample of blood, using a first reagent, and measuring basophils in a second sample of blood using a second reagent.[9]

The present invention addresses the deficiencies of the prior art and provides a single-solution[10] reagent that facilitates the determination of haemoglobin, total leucocytes, and the basophil subpopulation.[11] The inventive reagent does not comprise cyanic compounds.[12] The inventive reagent comprises: a buffer system to establish and maintain a pH lower than 3.0,[13] preferably a value of 2.4.[14] The buffer is a key constituent, inasmuch as the low pH permits the identification of the basophilic subpopulation.[15] The inventive reagent further comprises a cationic detergent[16] chosen for its effectiveness to lyse erythrocytes.[17] The cationic detergent is advantageously a quaternary ammonium complex.[18] The inventive reagent further comprises a nitrogenous compound chosen to stabilize the by-products of the oxidation of haemoglobin.[19] The reagent may further comprise at least one inorganic salt.[20]

Appellant submits that the various individual components of the inventive composition, severally, were known *per se*. However, what was not known, or described in the cited references, was the specific combination of the various agents together in a single composition.

VI. Grounds of Rejection.

Claims 12 and 14-24 were rejected under 35 U.S.C. § 112(1st) as failing to comply with the written description requirement.

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[8] Page 2, lines 15-28.
[9] Page 2, lines 15-19. (The prior art teaches a reagent for measurement of haemoglobin and total, undifferentiated leucocytes) (Page 3, lines 14-18).
[10] Page 4, lines 15-28.
[11] Page 4, lines 1-5.
[12] Page 4, lines 16-17.
[13] Page 4, lines 27-29.
[14] Page 5, lines 14-15.
[15] Page 5, lines 1-4.
[16] Page 4, line 31.
[17] Page 5, lines 33-34.
[18] Page 6, lines 10-11.
[19] Page 6, lines 25-27.
[20] Page 6, lines 33-34.

Claims 12 and 14-24 were rejected under 35 U.S.C. § 103(a) as being unpatentble over US 5,538,893 in view of US 5,389,549.

VII. Arguments.

A. Claims 12 and 15-24.

Respecting Claims 12 and 15-24, a cationic detergent, a nitrogenous compound, the absence of cyanotic compounds, and a buffer composition sufficient to maintain a pH of below 3.0, were individually known to the art. However, their specific use together in a single-solution composition has not been described in the prior art cited by the examiner. Respecting Claim 14, the same inventive combination and additionally a pH of 2.4 is unknown in the art. The novelty of the claimed composition is conceded by the examiner. "Sakata et al differ from the instant invention in failing to disclose the single reagent as having a pH of 2.4 and further comprising a nitrogenous compound."[21] Thus, we begin the patentability analysis from the position that no one ever before combined the various agents into a single analytical composition at a suitable pH. However, the examiner contends that the inventive single-solution composition is *prima facie* obvious under 35 U.S.C. § 103, for the reasons set forth in the outstanding Office Action, which are summarized herein (*infra*).

The examiner rejects all of the claims in Appellant's application based on the combination of two references: Sakata et al. (U.S. 5,538,893) and Hamaguchi *et al.* (5,389,549). Sakata specifically describes and claims at least one nonionic detergent and at least one cationic detergent[22], of the quaternary ammonium type[23], and a pH value of 2.5 to 4.0.[24] Hamaguchi discloses reagents, each comprising two solutions[25] and further teaches anionic[26] and nonionic detergents and nitrogenous compounds. Hamaguchi further teaches the unsuitability of quaternary ammonium compounds for purposes of the invention.[27] The examiner asserts, as a conclusory statement, the obviousness of adding the nitrogenous compound of Hamaguchi to the solution of Sakata. The present invention teaches the use of a nitrogenous compound to stabilize the by-products of the oxidation of haemoglobin. Each of Sakata and Hamaguchi is silent as to

[21] *See*, Final Office Action, page 5, lines 13-14.
[22] Sakata, col. 2, line 21.
[23] Sakata, col. 4, lines 20-22.
[24] Sakata, col. 2, line 22.
[25] Hamaguchi, col. 17, lines 27-30.
[26] Hamaguchi, col. 7, lines 43-47.
[27] See *infra*.

the determination of haemoglobin. Appellant questions the examiner's reliance, in the absence of evidence intrinsic to the references, on the obviousness of selecting of various agents which are used for *different* purposes.

Appellant submits that the threshold issue becomes whether the examiner has carried the legal burden to establish a case of *prima facie* obviousness against Appellant's claimed composition. In other words, do the cited references motivate a skilled worker to select and combine the various agents into a single analytical composition with a reasonable expectation that if this were done, a successful result would be obtained? For at least the reasons detailed below, Appellant respectfully submits that the examiner has not met that burden, and therefore, no case of *prima facie* obviousness has been established against the claims. Accordingly, the rejections are improper and should be withdrawn.

1. Whether the prior art would have suggested to those of ordinary skill in the art that they should make the claimed composition.

"Where claimed subject matter has been rejected as obvious in view of a combination of prior art references, a proper analysis under §103 requires, *inter alia*, consideration of two factors: (1) whether the prior art would have suggested to those of ordinary skill in the art that they should make the claimed composition or device. [T]he suggestion... must be founded in the prior art, not in the Appellant's disclosure."[28] In the case of a patent based on the combination of two known elements, "[t]here is no basis in the law ... for treating combination inventions any different than other inventions." *Fromson v. Advance Offset Plate, Inc.*[29] (holding that the combination of three known separate process steps into a single step is nonobvious); *Brentingson Fishing Equipment Co. v. Shimano American Corp.*,[30] ("the focus under section 103 is not whether each element in a claimed invention is old and unpatentable, but whether there is something in the prior art as a whole to suggest the desirability, and thus the obviousness, of making the combination."); *Connell v. Sear, Roebuck & Co.*,[31] ("There is no [separate statutory] classification entitled *combination patents*. Virtually every invention is a combination of elements or process steps.") (emphasis in original)

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[28] *In re Vaeck*, 947 F.2d 488, 493 (Fed. Cir. 1991) (citation omitted).
[29] 755 F.2d 1549, 1556 (Fed. Cir. 1985).
[30] 8 U.S.P.Q. 2d 1669, 1672 (Fed. Cir. 1988).
[31] 722 F.2d 1542, 1549 (Fed. Cir. 1983).

The court has repeatedly struck down PTO and Board decisions rejecting claims under section 103 where there is no suggestion or motivation in the prior art to combine the teachings of the two or more cited references. This is especially true in the context of combination inventions. In such cases, the court often finds that the PTO and Board improperly asserted a *prima facie* case of obviousness based on the teachings of the Appellant's own disclosure. *In re Rouffet.*[32]

> "As this court has stated, 'virtually all inventions are combinations of old elements.' *** Most, if not all, inventions are combinations and mostly of old elements. Therefore an examiner may often find every element of a claimed invention in the prior art. If identification of each claimed element in the prior art were sufficient to negate patentability, very few patents would ever issue. Furthermore, rejecting patents solely by finding prior art corollaries for the claimed elements would permit an examiner to use the claimed invention itself as a blueprint for piecing together elements in the prior art to defeat the patentability of the claimed invention. Such an approach would be 'an illogical and inappropriate process by which to determine patentability.'"
>
> "To prevent the use of hindsight based on the invention to defeat patentability of the invention, this court requires the examiner to show a motivation to combine the references that create the case of obviousness. In other words, the examiner must show reasons that the skilled artisan, ... with no knowledge of the claimed invention, would select the *elements* from the cited prior art references *for combination in the manner claimed.*" (emphasis added)

The Court in *Rouffet* tells us that one skilled in the art must be motivated by some teaching in the references to make the specific combination claimed. *See*, also *In re Dembiczak* [33] ("the standard established by section 103 requires the oft-difficult but critical step of casting the mind back to the time of invention, to consider the thinking of one of ordinary skill in the art, guided only by the prior art references and the then accepted wisdom in the field.").

The combination of two known components to make a novel composition has been held by the court to be non-obvious. *In re Jones.*[34] In *Jones*, the court reversed the Board's decision rejecting the claims as prima facie obvious because the Board failed to identify any suggestion in the cited references, or in the knowledge generally available, to combine the two components in a single composition. The invention was directed to the combination of dicamba (a

[32] 149 F.3d 1350 (Fed. Cir. 1998).
[33] 50 U.S.P.Q. 2d 1614 (Fed. Cir. 1999).
[34] 958 F.2d 347 (Fed. Cir. 1992).

substituted benzoic acid) and a specific ammonium cation derived from the amine, 2-(2'-aminoethoxy) ethanol. The primary reference broadly disclosed substituted ammonium salts of dicamba. The secondary reference disclosed the claimed ammonium cation for use with various surfactants. However, nowhere in the art was the specific combination of the two agents ever suggested. The court went on to state: "Conspicuously, missing from the record is any evidence, other than the PTO's speculation (if it be called evidence) that one of ordinary skill in the herbicidal art would have been motivated to make the modifications of the prior art salts necessary to arrive at the claimed 2-(2'-aminoethoxy) ethanol salt." [35] *Id.* at 351.

The present invention teaches the use of a nitrogenous compound, such as a thiourea,[36] to stabilize the by-products of the oxidation of haemoglobin.[37] Each of Sakata and Hamaguchi is silent as to the analysis of haemoglobin. Therefore, the motivation cannot be present in the prior art in a context similar to that of the present invention. The Examiner acknowledges Sakata to be silent as to a nitrogenous compound.[38] Therefore, any such suggestion must be found in Hamaguchi. Hamaguchi teaches thiourea as a solubilizing agent.[39] The Examiner suggests that it "would have been obvious...to incorporate the solubilizing agent / nitrogenous compound as taught by Hamaguchi into the single reagent as taught by Sakata because Hamaguchi specifically suggested conventional applicability of nitrogenous compounds with hematologic reagents used in leucocyte classification.[40] However, Hamaguchi does not provide motivation to combine a nitrogenous compound with the reagents of Sakata. Sakata is based on optical methods of detection.[41] Hamaguchi teaches that solubilization is a complex phenomena and that various reagents cannot simply be mixed *ad hoc*. For example, Hamaguchi teaches that the prior art utilizes

> an optical apparatus for measurement. Since these methods employ a completely different principle of measurement than the methods of the present invention, needless to say the reagents disclosed in the above-mentioned patents cannot be directly applied to the methods of the present invention whose operating principle is detection of impedance.[42]

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[35] 958 F.2d 351.
[36] Claim 18.
[37] Page 6, lines 25-27.
[38] Final Office Action, page 5, lines 13-14.
[39] Hamaguchi, col. 11, lines 38-41.
[40] Final Office Action, page 6, lines 5-10. (Emphasis added).
[41] *See* Figures 1-13 relating to high and low angle light scattering, and Figure 14 relating to the optical system.
[42] Hamaguchi col. 16, lines 24-31.

Hamaguchi expressly teaches that one cannot merely substitute reagents used for optical detection assays in electrochemical assays. Moreover, Hamaguchi teaches that not all solubilizing agents are suitable even for different types of hematologic assay:

> In addition, according to the experiments conducted by the present inventor, some of the polyoxyethylene-based surfactants disclosed in those prior patents are not only unsuitable for use in the methods of the present invention for leukocyte classification but also lack the ability to dissolve erythrocytes.[43]

Here Hamaguchi expressly teaches that there can be no motivation simply to combine reagents merely because they may bear some relationship to hematologic assay. There is yet a further reason that a person of skill would not fine in Hamaguchi any expectation that the components of the Hamaguchi invention could be combined successfully with the components of the Sakata invention to yield the present invention. Sakata relates to cationic detergents[44] and specifically to quaternary ammonium compounds.[45] The present invention similarly relates to cationic detergents,[46] preferably quaternary ammonium compounds.[47] In contradistinction, Hamaguchi relates to anionic detergents.[48] Further, Hamaguchi specifically excludes quaternary ammonium compounds.[49] Moreover, Hamaguchi nowhere suggests that agents suitable for use with anionic detergents are necessarily suitable for use with cationic detergents.

The Federal Circuit's admonition that combinations of old elements (*i.e.*, elements *per se* taught in the art even for the same purpose as claimed) can still be patentable was restated in *The Gillette Company v. S. C. Johnson & Son, Inc.*[50]:

> It is true that [the claimed invention] consists of a combination of old elements so arranged as to perform certain related functions. It is immaterial to the issue, however, that all of the elements were old in other contexts. *What must be found obvious to defeat the patent is the claimed combination.*

And the Court carefully distinguished the legal standard of obviousness from "obvious to try":

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[43] Hamaguchi col. 16, lines 31-36.
[44] Sakata, col. 2, line 21.
[45] Sakata, col. 4, line 20-22.
[46] Page 13, line 12.
[47] Page 14, lines 7-8.
[48] Hamaguchi, abstract.
[49] Hamaguchi, col. 14, lines 6-9.
[50] 15 U.S.P.Q.2d 1923 (Fed. Cir. 1990)

> [a]n "obvious-to-try" situation exists when a general disclosure may pique the scientist's curiosity, such that further investigation might be done as a result of the disclosure, but the disclosure itself does not contain a sufficient teaching of how to obtain the desired result, or that the claimed result would be obtained if certain directions were pursued. *** However, we have consistently held that "obvious to try" is not to be equated with obviousness under 35 USC 103.

See also In re Fine, [51](no *prima facie* obviousness; "obvious to try" is "not a legitimate test of patentability"); and *In re Tomlinson*,[52] (patentability determinations based upon obviousness to try is contrary to the statutory standards under 103).

2. Whether the prior art would have suggested to those of ordinary skill in the art that the proposed combination carried a reasonable expectation of success?

A proper analysis under §103 requires, *inter alia*, consideration of two factors: (1) whether the prior art would have suggested to those of ordinary skill in the art that they should make the claimed composition or device, or carry out the claimed process; and (2) whether the prior art would also have revealed that in so making or carrying out, those of ordinary skill would have a reasonable expectation of success. Both the suggestion and the reasonable expectation of success must be founded in the prior art, not in the Appellant's disclosure." [53]

The teachings of Sakata and Hamaguchi conflict, such that a person of skill in the art would not have a high expectations that their combination would be successful. Sakata discloses solutions containing at least one cationic detergent.[54] Moreover, Sakata requires the cationic detergent to be a quaternary ammonium compound.[55] The present invention requires at least one cationic detergent, preferably a quaternary ammonium compound. However, Hamaguchi teaches:

> Thus, it is entirely meaningless to use a quaternary ammonium salt as a cytolytic agent in a method of classifying leukocytes by the combination of the Rf and DC methods.[56]

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[51] 5 U.S.P.Q.2d 1596, 1598-9 (Fed. Cir. 1988).
[52] 363 F.2d 928 (C.C.P.A. 1966).
[53] *In re Vaeck*, 947 F.2d 488, 493 (Fed. Cir. 1991) (citation omitted).
[54] Sakata, col. 2, line 21.
[55] Sakata, col. 4, lines 21-37. (Note the nitrogen in the pyridinium alternative is also a quaternary ammonium).
[56] Hamaguchi, col. 14, lines 6-9.

Hamaguchi here expressly teaches that a person of skill in the art would not ordinarily have an expectation that reagents suited to the determination of leucocytes by optical methods would be suitable for determinations by electrochemical methods. Moreover, neither Hamaguchi, nor Sakata, have any teaching that merely because a nitrogenous compound is effective with an anionic detergent that it is necessarily effective with a cationic detergent.

B. Claim 14.

Respecting Claim 14, the Appellant realleges and specifically incorporates by reference each argument advanced in support of the patentability of Claims 12 and 15-24.

Whether the combination suggested by the Examiner forms an inoperable combination and therefore teaches away from the invention.

With respect to the recitation of pH 2.4, the novelty of the claimed composition is conceded by the examiner. "Sakata et al differ from the instant invention in failing to disclose the single reagent as having a pH of 2.4 and further comprising a nitrogenous compound."[57] The Examiner cites Hamaguchi as teaching a pH range of from 1.5 to 5.0 thereby encompassing the pH of the instant invention. However a pH value less that 2.5 is makes the invention of Sakata inoperable:

> The pH value of the reagent of the present invention is maintained by using a buffer in the range from 2.5 to 4.0, preferably from 3.0 to 4.0. If the pH value is less than 2.5, the nuclei of immature granulocytes and mononuclear cells are easily bared. Accordingly, it would be difficult to distinguish leukocytes into each subclass. If the pH value is greater than 4.0, few leukocytes will be shrunk and their nuclei made naked, and few erythrocytes and blood platelets are shrunk and hemolysed.[58]

Sakata expressly teaches the unsuitability of pH values lower than 2.5.

Where the Examiner proposes a combination that makes a prior art reference inoperable for its intended purpose, the resulting inoperable prior art reference is considered to teach away from the proposed combination, thereby supporting a showing of nonobviousness. *In re Gordon*,[59] (Finding no suggestion to modify a prior art device where the modification would make the device inoperable for its intended purpose); *TecAir, Inc. v. Denso Mfg. Michigan Inc.*,[60] (Holding that because the combination was inoperable for its intended purpose, a jury could reasonably

[57] *See*, Final Office Action, page 5, lines 13-14.
[58] Sakata, col. 5, lines 25-30.
[59] 733 F.2d 900, 902 (Fed. Cir. 1984).
[60] 192 F.3d 1353, 52 USPQ 2d 1294, 1298 (Fed. Cir. 1999).

find the patent taught away from the combination); *In re Sponnoble*,[61] (Holding if where combined, the references would produce a seemingly inoperative device, the references teach away from their combination).

C. Conclusion.

The mere fact that prior art may be modified in the manner suggested by the Examiner does not make this modification obvious, unless the prior art suggests the desirability of the modification. No such suggestion appears in the prior art in this matter. The Examiner's attention is kindly directed to *In re Gordon*,[62] ; *In re Laskowski*;[63] and *In re Fritch*.[64]

Concerning the above rejection of the claims, the Examiner should be mindful of the following cautionary statement made by the Court in *Grain Processing Corp. v. American Maize-Products Corp.*[65] :

> Care must be taken to avoid hindsight reconstruction by using the patent in suit as a guide through the maze of prior art references, combining the right references in the right way so as to achieve the same result of the claims in suit.

Likewise, as stated by the court in *Interconnect Planning Corp. v. Feil*:[66]

> It is error to reconstruct the patentee's claimed invention from the prior art by using the patentee's claim as a blueprint. When prior art references require selected combination to render obvious a subsequent invention, there must be some reason for the combination, other than the hindsight obtained from the invention itself. It is critical to understand the particular results achieved by the new combination.

In the present situation, no such reasoning for the combination exists in the prior art, and nothing in the prior art would suggest the properties achieved by the present invention. Also, see *In re Fine*,[67] wherein the Court stated that "one cannot use hindsight reconstruction to pick and choose among isolated disclosures in the prior art to deprecate the claimed invention." Moreover, it is important to keep in mind that statements in the prior art should not be read out of context when evaluating obviousness. See *In re Wright*.[68]

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[61] 405 F.2d 578, 587 (CCPA 1969).
[62] 221 USPQ 1125 (Fed. Cir. 1984).
[63] 10 USPQ2d 1397 (Fed. Cir. 1989).
[64] 23 USPQ2d 1780 (Fed. Cir. 1992).
[65] 5 USPQ2d 1788 (Fed. Cir. 1988).
[66] 227 USPQ 543 (Fed. Cir. 1985).
[67] 5 USPQ2d 1596 (Fed. Cir. 1988).
[68] 9 USPQ2d 1649 (Fed. Cir. 1989).

The prior art lacks the necessary direction or incentive to those of ordinary skill in the art to render a rejection under 35 USC 103 sustainable. The prior art fails to provide the degree of predictability of success of achieving the properties attained by the present invention needed to have a rejection under 35 U.S.C. 103 sustained. See *In re Mercier*,[69] and *In re Naylor*.[70]

Moreover, the properties of the subject matter and improvements which are inherent in the claimed subject matter and disclosed in the specification are to be considered when evaluating the question of obviousness under 35 USC § 103. See *Gillette Co. v. S.C. Johnson & Son, Inc.*;[71] *In re Antonie*;[72] *In re Estes*;[73] and *In re Papesch*.[74]

No property can be ignored in determining patentability and comparing the claimed invention to the prior art. Along these lines, see *In re Papesch*, supra, *In re Burt et al.*;[75] *In re Ward*;[76] and *In re Cescon*[77].

The above discussion renders it abundantly clear that the Primary Examiner erred in finally rejecting claims 12 and 14-24. Therefore, the undersigned respectfully requests the Board to reverse the Examiner and grant claims 12 and 14-24.

Respectfully submitted,

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[69] 187 USPQ 774 (CCPA 1975).
[70] 152 USPQ 106 (CCPA 1966).
[71] 16 USPQ2d 1923 (Fed. Cir. 1990).
[72] 195 USPQ 6 (CCPA 1977).
[73] 164 USPQ 519 (CCPA 1970).
[74] 137 USPQ 43 (CCPA 1963).
[75] 148 USPQ 548 (CCPA 1966).
[76] 141 USPQ 227 (CCPA 1964).
[77] 177 USPQ 264 (CCPA 1973).

APPENDIX A
AMENDED CLAIMS ON APPEAL

1-11. (Cancelled)

12. A single reagent for the simultaneous determination of total leucocytes, and basophile polymorphonuclear leucocytes, and for the measurement of hemoglobin in a sample of blood, said reagent comprising:

a buffer suitable to adjust and maintain the pH to a value lower than 3;
at least one cationic detergent;
a nitrogenous compound; and further comprising
the absence of cyanic compounds.

13. (Cancelled)

14. The single reagent of claim 12, wherein said buffer adjusts the pH to a value of 2.4.

15. The single reagent of claim 12, wherein said buffer is a multi-component mixture selected from the group of mixtures consisting of:

potassium chloride plus hydrochloric acid,
tartaric acid plus sodium hydroxide,
citric acid plus sodium hydroxide,
potassium hydrogen phthalate plus hydrochloric acid,
citric acid plus disodium hydrogen phosphate, and
boric acid plus citric acid plus potassium dihydrogen phosphate.

16. The single reagent of claim 12, wherein said detergent is selected from the group consisting of primary amines, acetates of fatty amines, hydrochlorides of fatty amines, quaternary ammonium salts, trimethylethylammonium bromide, and amides of cyclized diethylenetriamine.

17. The single reagent of claim 12, wherein said detergent comprises amides of substituted diamines wherein said substituted diamines are cationized by a compound selected from the group consisting of ethyl sulfate, diethanolaminopropylamine, and diethylaminopropylamide.

18. The single reagent of claim 12, wherein said nitrogenous compound is a thiourea.

19. The single reagent of claim 18, wherein said thiourea is 1,3-dimethyl-2-thiourea.

20. The single reagent of claim 12 further comprising at least one inorganic salt.

21. The single reagent of claim 20, wherein said at least one inorganic salt is an alkali metal salt.

22. The single reagent of claim 20, wherein said at least one inorganic salt is a chloride or sulfate of sodium or potassium.

23. The single reagent of claim 12, wherein said detergent is present at a concentration of 0.2 - 20 g/l and the nitrogenous compound is present at a concentration of 0.1-10 g/l.

24. The single reagent of claim 12 comprising:
5 - 10 g/l potassium chloride;
0.5 - 3 g/l 1,3-dimethyl-2-thiourea;
0.5 - 5 g/l dodecyltrimethylammonium chloride; and
1.0 - 10 g/l potassium hydrogen phosphate plus hydrochloric acid.

25. (Cancelled)